SEP 2 6 2002

K023113

510(k) Summary of Safety and Effectiveness

Submitted by:	Herbert Crane, Manager Regulatory Affairs
Address:	Nobel Biocare USA, Inc. 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone: Fax:	(714) 282 4800 x5074 (714) 998 9348
Date of Submission:	18 Sept. 2002
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Replace TiUnite Endosseous Implant
Legally Marketed Device:	Modified Surface Implant (K993595)

Device Description:
The Replace TiUnite endosseous implant is a threaded root-form dental implant. It comes in widths of 3.5mm, 4.3mm, 5.0mm, and 6.0mm. Each width comes in lengths of 10mm, 13mm, and 16mm. The surface of the threaded portion of the implant has a titanium oxide layer that is uniformly thin (mean<10μ).

Indications for Use:
The Nobel Biocare Replace TiUnite Endosseous Implant is intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

If the single stage procedure is used, these implants may be loaded immediately following insertion – provided – at least four implants are placed, and are splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foramina) where good initial stability of the implants, with or without bi-cortical anchorage, can most often be obtained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2002

Mr. Herbert Crane
Manager, Regulatory Affairs
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K023113
Trade/Device Name: Replace TiUnite Endosseous Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 18, 2002
Received: September 19, 2002

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K023113**

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023113

(Optional Format 3-10-98)